JUN 2 7 2001

K011299

510(k) Summary
Smith & Nephew 5.0mm Absorable Polymer Anchor
Date Prepared: April 26, 2001

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Tim Crabtree
Regulatory Affairs Specialist

C. Device Name

Trade Name: TBD
Common Name: Absorbable Suture Anchor
Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue

D. Predicate Devices

Zimmer 5.0mm Bio-Statak (K961789)
Arthex Bioabsorable Corkscrew Suture Anchor (K990987)
Smith & Nephew BioRCI Screw (K992396)

E. Description of Device

The Smith & Nephew 5.0mm Absorbable Polymer Anchor is manufactured using poly(L-lactide). The anchor is a threaded design with (2) two eyelets, to which a braided absorbable or non-absorbable suture is attached, one per eyelet. A bi-lobed broach hole at the proximal end of the anchor accepts a disposable driver, which is used as the insertion device. The anchor requires a tapping procedure prior to implantation. Following implantation of the anchor, the free ends of the suture are used to reattach soft tissue to bone.

F. Intended Use

The Smith & Nephew 5.0mm Absorbable Polymer Anchor is intended for use only for the reattachment of soft tissue to bone for the following indications:

Shoulder:
1. Bankart lesion repairs
2. SLAP lesion repairs
3. Acromioclavicular separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

Foot and Ankle:
1. Hallux valgus repairs
2. Medial or lateral instability repairs/reconstructions
3. Achilles tendon repairs/reconstructions
4. Midfoot reconstructions
5. Metatarsal ligament/tendon repairs/reconstructions

Elbow, Wrist, and Hand:
1. Scapholunate ligament reconstructions
2. Ulnar or radial collateral ligament reconstructions
3. Lateral epicondylitis repair
4. Biceps tendon reattachment

Knee:
1. Extra-capsular repairs:
   a. medial collateral ligament
   b. lateral collateral ligament
   c. posterior oblique ligament
2. Iliotibial band tenodesis
3. Patellar realignment and tendon repairs, including vastus medialis obliquous advancement

Comparison of Technological Characteristics

The Smith & Nephew 5.0mm Absorbable Polymer Anchor is substantially equivalent in design, function and intended use to the Zimmer 5.0mm Bio-Statak Anchor and Arthrex Bioabsorbable Corkscrew Suture Anchor. It is substantially equivalent in its materials to the Smith & Nephew BioRCI Screw and Zimmer Bio-Statak Anchor.

Tim Crabtree

Regulatory Affairs Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Timothy Crabtree
Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, Massachusetts 01810

Re: K011299
Trade Name: Smith & Nephew 5.00 mm Absorbable Polymer Anchor
Regulation Number: 888.3030
Regulatory Class: II
Product Code: MAI
Dated: April 27, 2001
Received: April 30, 2001

Dear Mr. Crabtree:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

K011299

510(k) Number :

Device Name: Smith & Nephew 5.0mm Absorbable Polymer Anchor

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(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter ____
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011299